

NOV - 4 1997

510(K) SUMMARY**Submitter's Name:**

Imatron, Inc.

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South San Francisco, CA 94087**Phone(s):**(O) 415-583-9964, ext. 206
(F) 415-827-7790**Contact Person:**

J.A. Coduto

Date:

August 8, 1997

Common Names:Workstation, Image Processing Workstation,
and Image Workstation**Proprietary Names:**Imatron Ultra Access® Workstation with Cardiac
Software Extensions**Classification Name:**

No classifications have been specifically issued for PACS or PACS components. For purposes of determining substantial equivalence workstations are considered to be accessories to medical imaging devices.

The Imatron Ultrafast CT scanner is such an imaging device and, as such, is Class II (reference: 21 CFR section 892.1750). Imatron's Ultra Access Workstation is similarly classified.

Predicate Device:

Predicate devices include: the C150XP's Physician Workstation as a component of the Imatron scanner (an Imatron, Inc. product); the NetraMD Workstation (a ScImage, Inc. product); the AIDP (Acculmage, Inc. Image Display Processor) Imatron/DICOM Image Processing Workstation (an Acculmage, Inc. product); and the VRSAPP Workstation (an ISG Technologies product).

Device Description:

Device Description

The Imatron Ultrafast CT Scanner --

The Imatron Ultrafast CT scanner is a scanning system (like those generically described in 21 CFR section 892.1750, which deals with "computed tomography X-ray systems") which operates by directing a focused beam of electrons along tungsten target rings to produce X-rays which pass through the body at multiple angles as in conventional CT scanning systems.

The Imatron Ultrafast CT scanner is capable of producing CT slices at rapid speeds since the data is produced by electronic rotation of the electron beam itself rather than the mechanical rotation of an X-ray tube as in conventional CT scanning systems.

Currently, the Imatron Ultrafast CT scanner operating at its highest resolution mode has 864 single or paired, contiguous X-ray detectors subtending an arc of 0.250 degrees each. The resulting 5% amplitude modulation transfer function (MTF) for high contrast objects at the center of the circle of reconstruction is 7 line pairs per centimeter (lp/cm).

Such scanner has the current ability to receive, manipulate, transmit, store, view, characterize, compare and enhance medical images.

The ISG Workstation --

The ISG Workstation is a device for picture

archiving and communications cleared for use in processing and displaying medical images on a monitor, storing medical image data on fast access media, i.e. hard disk, and on slow access media, i.e. archive media, and transmitting data over local and wide area networks.

The Significant Modification

The **only** change Imatron is making to ISG's Workstation is the addition of a software package. This package is in addition to (not an amendment of) the software package currently provided with the ISG Workstation. Such package is described in detail within this 510(k) submission, as is the Workstation's intended use.

Intended Use:

The Imatron Ultra Access Workstation is intended as an accessory to Imatron's Ultrafast Computed Tomography (CT) Scanner, a cleared device. The Ultra Access Workstation accepts data from Imatron's Ultrafast CT scanner and allows for advanced post processing of such data.

Thus, as modified from the ISG Workstation, the Imatron Ultra Access Workstation is intended – as are the predicate devices – for receiving, manipulating, transmitting, storing, viewing, characterizing, comparing and enhancing high quality CT electronic images, as an aid in diagnosis, including for cardiac analysis, by a trained physician.

Technological Characteristics:

See attached Substantial Equivalence Comparison and Explanation of Differences

Performance:

Although there are no performance standards established by FDA for PACS devices, the Ultra Access Workstation has been designed and manufactured to meet: the ACR/NEMA Digital Imaging and Communications in Medicine (DICOM) Standard, version 3.0; and the ACR/NEMA DICOM 3.0 Digital Interchange Standard for Cardiology (DISC95-96). The device and its development

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process also comply with FDA's, August 29, 1991 guidance document titled: "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review".

Testing Conclusions:

The Ultra Access Workstation successfully passed all testing at Imatron. Such testing indicates that the device as described in this submission is substantially equivalent to predicated devices.

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

Following in tabular (Table 2) and explanation form is a comparison of the similarities and differences that exist between the subject device and the predicate devices.

TABLE 2: COMPARISON OF FEATURES AND SPECIFICATIONS

ITEM	FEATURE	ULTRA ACCESS DEVICE	C150 XP DEVICE	NETRA MD DEVICE	AIDP DEVICE	VRSAPP DEVICE
1	2D image review	Yes	Yes	Yes	Yes	Yes
	Multiplanar reformatting	Yes	Yes	Yes	Yes	Yes
	3D surface and volume rendering	Yes	No	Yes	Yes	Yes

ITEM	FEATURE	ULTRA ACCESS DEVICE	C150 XP DEVICE	NETRA MD DEVICE	AIDP DEVICE	VRSAPP DEVICE
	Maximum intensity projection	Yes	No	Yes	Yes	Yes
	Performance of CTA and MRA	Yes	No	Yes	Yes	Yes
	Image archiving	Yes	Yes	Yes	Yes	Yes
	Image filming	Yes	Yes	Yes	Yes	Yes
	Image transfer or network connectivity	Yes	Yes	Yes	Yes	Yes
2	Examination of 2D image data from a calcium scan	Yes	Yes	Yes	Yes	Yes
3	Examination of calcium scan as a 3D volume	Yes	No	Yes	Yes	No

ITEM	FEATURE	ULTRA ACCESS DEVICE	C150 XP DEVICE	NETRA MD DEVICE	AIDP DEVICE	VRSAPP DEVICE
4	Semi automated identification of regions that are considered calcium	Yes	No	Yes	Yes	No
5	User override of automatically identified regions	Yes	No	Yes	No	No
6	Automatic computation of calcium score	Yes	No	Yes	No	No
7	Ability to measure CT numbers on a 2D image	Yes	Yes	Yes	Yes	Yes
8	Identification of mistriggered slices	Yes	Yes	No	No	No
9	Saving of calcium data with patient exam data	Yes	Yes	Yes	No	No

ITEM	FEATURE	ULTRA ACCESS DEVICE	C150 XP DEVICE	NETRA MD DEVICE	AIDP DEVICE	VRSAPP DEVICE
10	Creation of a paper calcium report	Yes	No	Yes	No	No
11	Comparison of multiple scans	Yes	No	Yes	No	No
12	Identification of mistriggered TDA data	Yes	Yes	No	No	No
13	Deselection of a mistriggered image	Yes	Yes	No	No	No
14	Identification of regions for which TDA computation should be performed	Yes	Yes	No	No	No
15	Automatic creation of gamma-variate curve fit for TDA data	Yes	Yes	No	No	No
16	Computation of curve parameter	Yes	Yes	No	No	No
17	Computation of perfusion	Yes	Yes	No	No	No

ITEM	FEATURE	ULTRA ACCESS DEVICE	C150 XP DEVICE	NETRA MD DEVICE	AIDP DEVICE	VRSAPP DEVICE
18	Creation of a parametric image	Yes	Yes	No	No	No
19	Creation of a paper TDA report	Yes	No	Yes	Yes	No
20	Indications for use— general medical imaging workstation	Yes	Yes	Yes	Yes	Yes
21	Indication for use -- calcium	Yes	Yes	Yes	Yes	No
22	Indication for use -- TDA	Yes	Yes	No	No	No

EXPLANATION OF DIFFERENCES IN TABLE 2

ITEM 3: REFORMATTING VS. SHADED SURFACE DISPLAY. Reformatting and shaded surface display are both well accepted methods of examining volumetric data. Gray scale information is lost in a shaded surface display, but because we are looking at high-contrast areas (calcium vs. surrounding tissue), gray scale information is not required. This difference does not affect safety or efficacy.

ITEM 4: FOOTPRINT IDENTIFICATION VS. COLORED SHADED SURFACE. Large contrast difference exist between calcified regions and soft tissue. Therefore, these regions can be identified equally readily on a maximum intensity projection (footprint method) or in a shaded surface display. We have chosen to use a 3D display because the spatial relationships between calcified regions are more clearly observable in a 3D display, and thus calcified regions in arteries and in non-arteries can be more clearly identified. This difference does not affect safety or efficacy.

ITEM 9: SAVING OF 3D DESCRIPTIONS VS. ROIS. The location of calcified regions can be stored as a set of (x, y, z) coordinates or as a set of (x, y, slice position) coordinates. In an axial scanning modality like CT, slice position and the z coordinate are proportional, and thus this difference does not affect safety or efficacy.

ITEM 10: VIEWING OF REPORT DATA IN MICROSOFT WORD OR IN NETSCAPE. Both methods allow a user to view text and image data, and to print these data onto paper. This difference does not affect safety or efficacy.

ITEM 11: VIEWING OF DUAL-SCANS ON SAME SHEET OR ON TWO-DIFFERENT SHEETS. Both methods allow for side-by-side comparison of two calcium scans. No functional difference is obtained by using two sheets of paper or one. This difference does not affect safety or efficacy.

ITEM13: USE/NO-USE VS. CLICKING ON AN IMAGE TO INDICATE DESELECTION. Both methods allow the user to tell the software which images to ignore when performing the subsequent gamma-variate curve fit. Ultra Access uses a more graphical approach (clicking on the image) to make it easier for the user to determine which slices were deselected and which were not. This difference does not affect safety or efficacy.

ITEM 17: SUPPORT OF 1 PERFUSION ALGORITHM OR 4. Ultra Access supports the perfusion algorithm used in the predicate device's software. However, as shown by the attached scientific references, other newer algorithms may yield more accurate results at higher flow states. Therefore, these additional algorithms have been provided. This difference does not affect safety or efficacy.

ITEM 18: GRAYSCALE VS. COLOR PARAMETRIC IMAGES. Both systems support grayscale mappings of curve parameter values. However, as the human eye can better perceive subtle changes in color than it can subtle changes in gray values, we have also provided color mappings. This approach is identical to that used in Nuclear Medicine or in PET scanning. We also support the colored display of perfusion. This parameter is being computed by the predicate device, but only being displayed as a number (as opposed to a colored map). Ease of use will be enhanced by displaying this additional parameter in color. This difference does not affect safety or efficacy.

ITEM 20: PAPER PRINTOUT MAP OF TDA REPORT. The predicate device creates paper reports describing the results of a calcium scan. In addition to supporting this type of printout in Ultra Access (see Item #10), Ultra Access will also create paper reports of TDA data. The data being placed on paper is identical to the data being computed by the C150XP predicate device, and therefore placing this information on paper (using a color inkjet printer to preserve color information) does not change its clinical meaning. This difference does not affect safety or efficacy.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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J. A. Coduto
Director, Regulatory Affairs
Imatron, Inc.
389 Oyster Point Blvd.
South San Francisco, CA 94080

Re: K972903
Imatron Ultra Access Workstation
with Cardiac Software Extensions
Dated: August 8, 1997
Received: August 6, 1997
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Coduto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3: PROPOSED INTENDED USE STATEMENT

The Imatron Ultra Access Workstation is intended as an accessory to Imatron's Ultrafast Computed Tomography (CT) Scanner, a cleared device. The Ultra Access Workstation accepts data from Imatron's Ultrafast CT scanner and allows for advanced post processing of such data.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972903

Prescription Use _____
(Per 21 CFR 801.109)